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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,279	01/17/2002	Alfred Bayati	1103326-0678	1319

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WHITE & CASE LLP  
PATENT DEPARTMENT  
1155 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036

EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/053,279

Applicant(s)

BAYATI, ALFRED

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/15/04</u> | 6) <input type="checkbox"/> Other: _____  |

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***Response to Amendment***

The amendment filed 10/15/2004 has been entered.

***Response to Arguments***

Any previous rejections that are not reiterated herein have been withdrawn.

Applicant's arguments with respect to claims 1-5 have been considered but are moot in view of the following new ground(s) of rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoeltje (US 5,912,235).

Hoeltje discloses a method of identifying a compound for treatment of gastric capacity disorders comprising administering a test compound (e.g., an erythromycin A compound) to a dog (i.e., a beagle) that has an impaired gastric capacity (note, the stomach is relaxed with the intake of liquids), determining the gastric capacity (or stomach volume) using a barostat (after constant pressure is achieved) and comparing the change in stomach volume in response to the test compound, see column 9, lines 21-60. The methods include determining the gastric capacity after a ramp phase. Note, in column 9, the method of determining the gastric capacity employs a barostat, which is the same device used for this step in the instant invention. Also, the method of Hoeltje specifically states stomach volume is measured at "constant pressure" see column 9. Thus, this would inherently be after a ramp phase, which would be the phase in which the pressure is increased to the plastic pouch in the stomach by the barostat until constant pressure is reached. Note, the methodology of determining gastric capacity as described in the specification of the instant invention, which has a ramp phase, is the same methodology used therefore

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by Hoeltje. Since constant pressure can not be achieved unless it is increased thereto, (e.g., this includes many factors, including stomach elasticity), then the methods of Hoeltje must determine the gastric capacity after a ramp phase (a phase of increasing pressure) to get to constant pressure, as disclosed in column 9. Note, the phase of constant pressure disclosed in the methods of Hoeltje would correspond to a tonic phase.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoeltje (US 5,912,235) in view of Ui (US 5,000,953).

Hoeltje discloses a method of identifying a compound for treatment of gastric capacity disorders comprising administering a test compound (e.g., an erythromycin A compound) to a dog (i.e., a beagle), as set forth above.

Hoeltje fails to disclose the use of a Wistar rat as the animal in the test.

However, the use of Wistar rats in such animal model methods are well known in the art as being equivalent to the use of a beagle dog for testing the efficacy of test drugs, as shown by Ui, see column 28, lines 23+.

It would have been obvious to one of ordinary skill in the art to substitute the beagles used in the test model method of Hoeltje with Wistar rats because it is known in the art that such rats may be used in an equivalent manner to dogs to provide animal model for testing the efficacy of a test drug, as shown by Ui. One of ordinary skill in the art would have been motivated to employ the equivalent rats to take smaller size.

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Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoeltje (US 5,912,235) in view of King (US 5,552,398)

Hoeltje discloses a method of identifying a compound for treatment of gastric capacity disorders comprising administering a test compound to a dog (i.e., a beagle), as set forth above.

Hoeltje fails to disclose the use of such a test model for other compounds (as claimed in claim 4) that are useful in treating dyspepsia.

King discloses compounds that are 5-HT-4 antagonists are potential compounds for treating dyspepsia, see column 3, lines 41+.

It would have been obvious to employ the methods disclosed by Hoeltje for testing the 5HT4 antagonists compounds disclosed by King because the Hoeltje methods determine if the test compounds can increase gastric capacity in conditions such as dyspepsia and King teaches new 5HT-4 antagonists which have potential for treating such conditions. One of ordinary skill in the art would have been motivated to test the compounds disclosed by King in methods disclosed by Hoeltje to see which compounds disclosed therein are most effective.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to describe the method as claimed wherein the step of determining the maximum gastric accommodation capacity..."wherein the determination is made after a ramp phase" because the genus of such a step is not fully described. More accurately, the determination is made after a ramp phase and during a tonic phase. The claim as now amended includes situations wherein the determination can be made any time

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after the ramp phase (e.g., which would include also after the tonic phase and after the end phase, that is anytime after the ramp phase). However, the specification only describes methods of making this determination after the ramp phase but during the tonic phase (e.g., which is prior to the end phase). Thus, the specification does not describe the breadth of the determination step as now claimed. This rejection may be obviated by amending the step of determination to "wherein the determination is made after a ramp phase and during a tonic phase..."

### ***Response to Arguments***

Applicant's arguments filed 10/15/2004 have been fully considered but they are not persuasive.

Applicant asserts that the prior art fails to disclose that the methods of determination are made after a ramp phase, as now claimed.

This is not found persuasive because, although the prior art i.e., Hoeltje does not specifically recite the term "ramp phase" the methods disclosed by Hoeltje include determination that is made which inherently encompasses such a phase, as described above. Hoeltje performs the determination at constant pressure using a barostat, which would inherently include being after a step of increasing the pressure to arrive a constant pressure, i.e., a ramp phase.

### ***Conclusion***

No claims are allowed at this time.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The thesis and abstract of Maria Nordling has been made of record on the IDS filed 10/15/2004. While this thesis (and possibly abstract) qualify as prior art based on the date of May 2000, these documents have not been deemed as qualifying as prior art at this time due to applicant statements filed with the IDS that, "The thesis was not distributed, nor was it housed or cataloged in the University library." However, more information concerning the abstract may be necessary, as no date for the abstract has been included on the PTO-1449, thus, this citation has been lined through. Also, more information may be

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required on the distribution of the abstract (number of persons, etc.). The following procedure is in accordance with MPEP 2128.02[R-2].

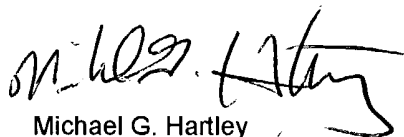
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael G. Hartley  
Primary Examiner  
Art Unit 1616

11/19/2004